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Nos. 03-1175 and 03-1178

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

VALLEY DRUG COMPANY and LOUISIANA WHOLESALE DRUG COMPANY, INC.,

Petitioners,

v.

GENEVA PHARMACEUTICALS, INC., *et al.*,

Respondents.

WALGREEN CO., *et al.*,

Petitioners,

v.

ABBOTT LABORATORIES, *et al.*,

Respondents.

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Should a settlement of *bona fide* patent litigation be condemned as a *per se* illegal horizontal market allocation, before meaningful discovery and without consideration of the settlement's relationship to the scope of the disputed patent rights or of the settlement's pro-competitive effects, solely on the basis that the infringer agreed to stay off the market for a small portion of the remaining patent term?

CORPORATE DISCLOSURE STATEMENT

Respondent Abbott Laboratories has no parent corporation and no publicly-held company owns more than 10% of its stock.

Respondent Geneva Pharmaceuticals, Inc. (now known as Sandoz Inc.) is indirectly owned by Novartis AG, whose stock is publicly traded.

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COUNTER-STATEMENT OF THE CASE

A. Nature of the Case

Respondent Abbott Laboratories developed and manufactures the branded drug Hytrin®, which is one of several drugs that treat hypertension and benign enlargement of the prostate. Hytrin's active ingredient is dihydrate terazosin hydrochloride. As a result of its research and development, Abbott received a number of patents covering various crystalline forms of terazosin hydrochloride. Respondent Geneva Pharmaceuticals, Inc. and numerous other companies filed applications with the Food and Drug Administration ("FDA") to market generic versions of Hytrin.

Pursuant to the Hatch-Waxman Amendments, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)), Abbott thereupon sued Geneva for infringement of a patent that did not expire until October 2014. Geneva admitted infringement but contested the patent's validity. To resolve the issue of interim relief preserving the status quo, Abbott and Geneva entered into an interim settlement in which Geneva agreed not to market its potentially infringing generic products pending final resolution of the litigation.[1]

Petitioners in No. 03-1175, Louisiana Wholesale Drug Company and Valley Drug Company, are two regional pharmaceutical wholesalers that purchased Hytrin from

1. Abbott also entered into a litigation settlement agreement with another generic manufacturer, Zenith Goldline Pharmaceuticals, Inc. Although Zenith was originally named as a defendant in these cases, Petitioners have abandoned their challenges to the Zenith agreement.

Abbott. They purport to represent a class of direct purchasers of Hytrin and generic terazosin. Petitioners in No. 03-1178 are Walgreen Co., Inc., CVS Meridian, Inc., Eckerd Corporation, Hy-Vee, Inc., Albertson's, Inc., Kroger, Co., the Stop & Shop Supermarket Co., and Rite Aid Corporation, large national retail chains that have purchased Hytrin directly from Abbott or from drug wholesalers who assigned their claims to Petitioners.

B. Hatch-Waxman Provides for Resolution of Patent Disputes Before Generic Marketing

The Petitions discuss at length the Hatch-Waxman Amendments governing the approval of generic drugs. However, the petitions are silent on the most relevant feature of Hatch-Waxman here – namely, that Hatch-Waxman provides for patent disputes like that between Abbott and Geneva to be resolved before a generic manufacturer begins marketing its product.

Specifically, when a generic company submits an Abbreviated New Drug Application ("ANDA"), it must file a certification to each patent listed by the pioneer company in an FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the generic company files a so-called "Paragraph IV" certification, which asserts that the patent is invalid or not infringed by the generic product (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), this is treated under Hatch-Waxman as an act of patent infringement (35 U.S.C. § 271(e)(2)) and the pioneer drug company may initiate infringement litigation. If the pioneer company does so within 45 days of notice of the certification, FDA approval of the generic is

delayed for 30 months or until the litigation is resolved at the appellate level in favor of the generic. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (c)(3)(C). This represents Congress' and the FDA's considered judgment that it is pro-competitive to defer generic marketing pending resolution of relevant patent disputes. *See, e.g.*, 21 U.S.C. § 355; 21 C.F.R. § 314, *et seq.*

C. Abbott's Inadvertent Failure to Sue Geneva In Connection With One of Its Terazosin ANDAs Led Directly to the Agreement at Issue

In April 1996, Geneva filed one ANDA seeking FDA approval to market generic terazosin hydrochloride *tablets* and another seeking approval to market generic terazosin hydrochloride *capsules*. Each ANDA included an identical Paragraph IV certification regarding Abbott's 5,504,207 patent (the "'207 patent"). In an oversight that led directly to the current litigation, Abbott did not notice that Geneva had served separate Paragraph IV certifications for both capsules and tablets. Thus, although Abbott filed a patent infringement action against Geneva before expiration of the 45-day period, Abbott mistakenly did so only on Geneva's *tablet* ANDA, but not on Geneva's *capsule* ANDA. Accordingly, the FDA was precluded from granting final approval to Geneva's tablet ANDA (until expiration of the 30-month stay), but could grant final approval to the capsule ANDA.

Abbott did not become aware of this situation until March 30, 1998, when Geneva communicated that it had obtained final FDA approval of its capsule ANDA. As of that date, the FDA would have permitted Geneva to come to market (subject to certain manufacturing problems and other issues that form the basis for a causation issue that the parties

are litigating in the District Court), even though Abbott held a presumptively valid patent that was admittedly infringed and had never been found to be invalid. Abbott immediately notified Geneva that it would seek to expand the pending patent litigation to cover Geneva's capsule product and began preparing motions for a temporary restraining order and preliminary injunction against Geneva's marketing its capsules. Abbott also began considering a judicial challenge to the FDA's decision to treat Geneva's capsule ANDA as unaffected by Abbott's suit regarding Geneva's tablets.

This situation created substantial legal and financial risks for both Abbott and Geneva. Abbott's risk was that if it failed to obtain preliminary relief, it would suffer enormous financial damages at the hands of a generic company that lacked sufficient capitalization to pay a judgment for Abbott's lost profits. Geneva faced tremendous risk regardless of whether Abbott obtained preliminary relief. If Abbott were to obtain a preliminary injunction following Geneva's market entry, Geneva would lose forever the benefit of its potential 180-day exclusivity period under Hatch-Waxman (because the statute provides no mechanism for tolling the exclusivity period once it has been triggered). If Abbott were denied a preliminary injunction, Geneva would risk ruinous damages if it marketed its capsule product and subsequently lost the '207 litigation. Conversely, by deferring the marketing until after the courts ruled on the validity of the '207 patent, Geneva would have the potential to maintain its right to 180-day exclusivity and to market its product free and clear from any infringement claim in the event the '207 patent was invalidated.

On April 1, 1998, against this background of mutual risk and the immediate prospect of Abbott's seeking preliminary

injunctive relief, Abbott and Geneva entered into an interim settlement agreement. In their agreement, the parties agreed to settle only the issue of preserving the status quo pending litigation in which the validity of the '207 patent would still be determined.

Like any settlement, the agreement reflected compromises by both sides. Geneva agreed not to market its terazosin products until after final judicial resolution of Abbott's patent infringement claim based on the '207 patent. As Geneva had not yet entered the market, Abbott obviously had no damage claim to compromise in exchange for Geneva's agreement not to market its product. Abbott instead agreed to monthly payments of $4.5 million to Geneva until the district court entered judgment in the pending lawsuit. If Abbott prevailed at this stage, no further payments would be made. If Geneva prevailed, however, Abbott would continue making payments into an escrow account until any appeals were resolved. The escrow funds ultimately were to be paid to the prevailing party.

The agreement substantially restored the parties to their position under Hatch-Waxman had Abbott not mistakenly failed to sue Geneva on its capsule product. The ultimate result was a reasonable implementation of the Hatch-Waxman policy – both sides would vigorously litigate the patent dispute and Geneva would not market its generic product until after the patent dispute was resolved.

After entering into their agreement, Abbott and Geneva did continue to litigate the patent dispute. In September 1998, after considering Geneva's summary judgment motion for approximately eighteen months, the district court issued the first judicial decision ever holding that any Abbott Hytrin

patent was invalid. In a "precedential" opinion, the Federal Circuit affirmed that decision in July 1999, and denied Abbott's petition for rehearing in August 1999. *See Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999). A few days later, Abbott and Geneva terminated the agreement, and Geneva launched its generic capsule product.

The Federal Trade Commission ("FTC") brought an administrative challenge to the Abbott-Geneva agreement, eventually resulting in consent settlements with both companies. In connection with its investigation and the settlements, the FTC did not suggest that the Abbott-Geneva agreement was illegal *per se* under the Sherman Act, and its complaint alleged only that the agreement was an unreasonable restraint of trade. *See* Complaint, *In the Matter of Abbott Labs. and Geneva Pharm., Inc.*, FTC Docket No. C-3945 (Mar. 16, 2000). The full Commission, in a unanimous statement in conjunction with the matters, recognized that each settlement of Hatch-Waxman litigation "must be examined with respect to its particular facts," *i.e.*, under the rule of reason. *Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary*, FTC Docket Nos. C-3945 and C-3946 (May 22, 2000).

D. Procedural History

The District Court held that the Abbott-Geneva agreement was *per se* illegal, before meaningful discovery had been conducted and without regard to the evidence of the circumstances surrounding the agreement. In an "appropriately narrow" decision (*Walgreen* Pet. App. 24a), the Eleventh Circuit reversed the *per se* ruling as "premature" and remanded for further proceedings.

In the more than three years since the District Court's initial ruling, the parties have now concluded extensive fact and expert discovery, including discovery on the issues identified as relevant by the Eleventh Circuit. Before the end of this month, briefing will be concluded on summary judgment motions that address the Abbott-Geneva agreement's ultimate legality or illegality – an issue that the Court of Appeals did *not* decide. Trial is scheduled for October 4, 2004.

REASONS FOR DENYING THE PETITION

I. IF THE COURT GRANTS REVIEW IN *ANDRX* (NO. 03-779), REVIEW SHOULD BE GRANTED IN THIS CASE AS WELL

The Petitions raise the issue of the appropriate antitrust framework for evaluating settlements of patent litigation in which the alleged infringer agrees not to market its product during a small portion of the remaining patent term. This issue is also raised in *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896 (6th Cir.), *petition for cert. filed sub nom. Andrx Pharm., Inc. v. The Kroger Co.*, No. 03-779 (Nov. 21, 2003) ("*Andrx*"). Petitioners in No. 03-1178 are respondents in *Andrx*. They affirmatively oppose *certiorari* both there and here, but argue that should this Court grant review in *Andrx*, it should also grant review here. Abbott and Geneva agree.

To be sure, there are key distinctions between the Abbott-Geneva agreement and the agreement at issue in *Andrx*. For example, the *Andrx* agreement precluded marketing of an actual generic product that *did not infringe any patent held by the brand name manufacturer. Valley Drug* Pet. App. 95a n.13. Here, by contrast, there was no evidence that any

generic manufacturer had a non-infringing product. On remand, in fact, all plaintiffs have conceded that no such product existed.

Nonetheless, any consideration by this Court of *Andrx* would likely involve determination of the appropriate antitrust framework for evaluating other Hatch-Waxman patent settlements. Thus, although Respondents believe that review of the Eleventh Circuit's decision would be premature at this juncture, if the Court were to grant *certiorari* in *Andrx* it should grant *certiorari* here as well.

II. The Petitions Should Be Denied To Allow Other Courts To Consider The Issue

As a general matter, "[t]he more important an issue is, the more the Court would benefit" by allowing the issue to develop in the lower courts. Robert L. Stern, Eugene Gressman, *et al., Supreme Court Practice* 457 (8th ed. 2002); *see also, e.g., McCray v. New York*, 461 U.S. 961, 963 (1983) (Opinion of Justice Stevens, joined by Justices Blackmun and Powell, respecting the denial of *certiorari*) ("[i]n my judgment it is a sound exercise of discretion for the Court to allow the various States to serve as laboratories in which the issue receives further study before it is addressed by this Court"). This principle applies with particular force here and counsels strongly against review.

A. Petitioners Seek Expansion of the *Per Se* Rule to a Type of Restraint With Which the Courts Are Just Beginning to Gain Experience

One of the most basic principles of antitrust law is that the rule of reason – that is, consideration of the purpose and competitive effects of the conduct at issue in the context of

the relevant market – is the presumptive mode of analysis. *See, e.g., California Dental Ass'n v. Federal Trade Comm'n*, 526 U.S. 756, 781 (1999); *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 726 (1988). By contrast, the *per se* rule, which squarely forecloses this sort of analysis, is limited to those "certain agreements or practices [that] are so 'plainly anticompetitive,' and so often 'lack . . . any redeeming virtue,' that they are conclusively presumed illegal without further examination." *Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 646 (1980) (*per curiam*); *see also California Dental Ass'n*, 526 U.S. at 758-59; *State Oil v. Khan*, 522 U.S. 3, 10 (1997); *Business Elecs. Corp.*, 485 U.S. at 731-35; *Northwest Wholesale Stationers, Inc., v. Pacific Stationery and Printing Co.*, 472 U.S. 284, 297-98 (1985); *National Collegiate Athletic Ass'n v. Board of Regents of Univ. of Okla.*, 468 U.S. 85, 101, 117 (1984); *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 70 (1977); *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

This Court has repeatedly cautioned against lightly expanding the categories of exceptions to rule of reason analysis. Rather, a conclusive presumption of illegality is applied only "[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." *Arizona v. Maricopa Cty. Med. Soc'y*, 457 U.S. 332, 344 (1983); *see also id.* at n.19 ("a *new per se* rule is not justified until the judiciary obtains considerable rule-of-reason experience with the particular type of restraint challenged"); *accord White Motor Co. v. United States*, 372 U.S. 253 (1963).

In this instance, however, the courts have no such experience on which to draw. While a number of similar cases

are currently pending in district and appellate courts, *see infra*, such challenges are as novel as the settlement agreements that they test. *See* Tr. of Status Hearing on April 16, 1999 at 7:11-8:1 (plaintiffs' counsel noting that "[t]his is really a case of first impression. . . . I think we are writing on a blank page here really"). In fact, as noted above, it is Congress' and the FDA's considered judgment that it is pro-competitive to delay generic marketing, as the Petitions allege the parties did here, pending resolution of patent disputes.[2] In this circumstance, the prudent course for this Court is to wait for the cases to develop further in the lower courts rather than grant review now.[3]

B. Other Cases Raising the Same Issue Are Proceeding in a Number of Circuits

The Petitions identify a split between just two circuits – the Eleventh Circuit in this litigation and the Sixth Circuit

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2. Petitioners emphasize that Hatch-Waxman was meant in certain respects to speed up approval of generic drugs – for example, by allowing generics to rely in their ANDAs upon the safety and efficacy data supplied in the innovator company's New Drug Application (*see* 21 U.S.C. § 355(j)(2)(A)(iv)). But this does not change the fact that Congress also specifically determined that it is pro-competitive to postpone generic marketing until after resolution of patent disputes.

3. Petitioners do not argue that there is substantial judicial experience with the type of agreement at issue. Instead, they point to a handful of scholarly articles as an imperfect alternative to judicial experience. Those articles, however, were all written after the cases arose, at least some by interested potential "expert" witnesses – including individuals plaintiffs have disclosed as testifying experts in the current litigation. They are no substitute for judicial experience.

in *Andrx*. Aside from these two proceedings, both of which arose on interlocutory appeal and both of which were decided on relatively limited records, no Court of Appeals has ruled on the issue presented. Moreover, no district court has completed a trial regarding the legality of a patent settlement in these circumstances under either a rule of reason or a *per se* theory.[4] Given the relief Petitioners seek (namely, expansion of the *per se* rule into a new area), the limited record before the courts in the two published appellate decisions to date, and the paucity of other decisions on point, the Court should allow the lower courts to proceed to judgment in the current litigation cases while a more substantial body of law develops in other courts.

Denial of *certiorari* at this stage would not unduly delay potential review of the issue. As previously noted, this litigation is set for trial on October 4, 2004. Unless the question presented in the Petitions is mooted by the results of the trial, petitions could be filed with this Court after the Circuit Court's review of the final judgment. Moreover, the slight delay would be well-spent. Other cases presenting the same or a similar issue are currently pending before other Courts of Appeals. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *appeal pending*, No. 03-7642 (2d Cir. June 20, 2003); *see also In re Schering-*

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4. Administrative trial experience is similarly limited. *In re Schering-Plough Corp.*, which is currently on appeal to the Eleventh Circuit, represents the "first time the Commission has addressed pioneer/generic patent settlements with the benefit of a full administrative trial and record." 2003 WL 22989651 (F.T.C.). Notably, the administrative law judge specifically rejected a *per se* rule, and in resolving the appeal, the Commission applied a rule of reason inquiry. *In the Matter of Schering-Plough Corp.*, 2002 WL 1488085; *In re Schering-Plough Corp.*, 2003 WL 22989651 (F.T.C.).

Plough Corp., 2003 WL 22989651 (F.T.C.), *appeal pending*, No. 04-10688 (11th Cir. Feb. 13, 2004). Moreover, unlike the litigation here and in *Andrx*, which involve agreements to maintain the status quo pending resolution of the litigation, other cases involve final settlements of patent litigation. *See, e.g.*, *Tamoxifen*, 277 F. Supp. 2d at 124; *In re Ciproflaxin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003). *Cf. In re Schering-Plough Corp.*, 2003 WL 22989651 (F.T.C.). Affording lower courts the opportunity to explore distinct but related factual scenarios will result in a more complete understanding of the impact a Supreme Court ruling in this area is likely to have. Accordingly, Respondents submit that this Court should deny review at this juncture as premature.

III. The Petitions Should Be Denied Because Review Is Not Appropriate On The Limited Record Now Before The Court On This Interlocutory Appeal

Granting review now would not only force the Court to forego the experience of other courts in resolving this issue, but it would also require reliance on an outdated and limited record in this case. This Court has held that *certiorari* is generally inappropriate in these circumstances, particularly when subsequent developments in a case could facilitate the Court's analysis or moot or alter the issue presented. *See American Constr. Co. v. Jacksonville, T. & K. West Ry. Co.*, 148 U.S. 372, 384 (1893) ("many orders made in the progress of a suit become quite unimportant by reason of the final result, or of intervening matters"); *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916) (interlocutory status of appeal "of itself alone furnished sufficient ground for the denial of the application").

Accordingly, interlocutory review by this Court is generally limited to situations in which "extraordinary inconvenience and embarrassment" justify interrupting the orderly disposition of a case. *American Constr. Co.*, 148 U.S. at 384.

The concerns that the Court has expressed with interlocutory review counsel against granting *certiorari* here. As noted, since this interlocutory appeal was filed, the case has progressed nearly to completion in the District Court. Fact and expert discovery have been completed on topics directly related to the issue that was the subject of interlocutory review. Summary judgment motions will be argued on July 2, 2004. *Daubert* motions relating to expert opinions on many of these topics will be argued later that same month. Trial is set for October 4, 2004.

The results of the motions or trial may well moot the issue that Petitioners ask the Court to review. For example, Respondents have raised causation defenses on the ground that the Abbott-Geneva agreement had no effect on competition because Geneva was unwilling and/or unable to launch its generic product even absent the agreement. If successful on summary judgment or accepted by the jury, such defenses would entirely moot the antitrust liability issues raised by the Petitions. The results of these further proceedings may also give rise to other issues that may ultimately merit review by this Court, thus raising the risk of piecemeal review. Petitioners in No. 03-1178 acknowledge all of these points in opposing review in the *Andrx* case. *See* Brief in Opposition, No. 03-779, at 21-23.

Simply put, where, as here, Petitioners have pointed to no extraordinary inconvenience that would result from a failure to consider this case at an interlocutory stage and

where the record underlying the District Court's decision is necessarily incomplete, review at this preliminary juncture should be denied.

IV. The Eleventh Circuit's Narrow Ruling Correctly Concluded That *Per Se* Liability Should Not Attach To An Interim Patent Settlement Where The Restraints Do Not Exceed The Exclusionary Scope Of The Patent

Commensurate with the "early stage of the litigation" on this interlocutory appeal, the Eleventh Circuit's ruling was "appropriately narrow" (*Walgreen* Pet. App. 24a): the Court of Appeals simply held that on the partial summary judgment record before it, the District Court had erred in holding the Abbott-Geneva agreement *per se* illegal under Section 1 of the Sherman Act without appropriate "consideration of the exclusionary potential of [Abbott's] patent." *Id.* at 37a; *see also id.* at 24a ("Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute *per se* violations of the antitrust laws must be reversed."). Notwithstanding Petitioners' protestations to the contrary, this holding was nothing more than a straightforward application of this Court's longstanding precedents governing the antitrust analysis of agreements affecting disputed patent rights.

As in the Court of Appeals, Petitioners seek here to characterize Geneva's agreement not to enter the market with its generic terazosin product as "an express, naked horizontal territorial restraint that has long been held *per se* illegal under Section 1 of the Sherman Act." *Valley Drug* Pet. 19 (citing

United States v. Topco Assoc., 405 U.S. 596, 608 (1972), and *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990)). The Court of Appeals correctly recognized, however, that the analogy of the Abbott-Geneva agreement to a naked horizontal restraint is fatally flawed because it fails to address the fundamental distinction that in *Topco, Palmer,* and every other case involving a "horizontal market allocation agreement," *no party claimed any pre-existing intellectual property-based right to exclude another from the market.*

Petitioners acknowledge (*Walgreen* Pet. 9; *Valley Drug* Pet. 14), as they must, that the antitrust analysis of agreements involving patents must begin with an examination of whether the challenged restraint exceeds the exclusionary scope of the patent right at issue. The Court of Appeals recognized that "the patent exception to antitrust liability" (*Walgreen* Pet. App. 37a) provides that where a challenged restraint does not exceed the scope of the patent, there can be no antitrust liability. The Court of Appeals further recognized, however, that "'the precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise.'" *Id.* (quoting *United States v. Line Material Co.*, 333 U.S. 287, 300 (1948)); *see also United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952) ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing], when the licenses are used, as here, in the scheme to restrain."); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant.").

The Court of Appeals held that once the comparison of the challenged restraints and the patent rights at issue is completed, any provisions of the agreement found by the District Court on remand to have "effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act." *Walgreen* Pet. App. 38a. On remand, the parties have been developing the factual and expert record necessary to permit the District Court to decide whether any aspect of the agreement's provisions in fact exceeded the scope of Abbott's patent rights. As noted above, those determinations will be made by the District Court in the near future. Thus, the ultimate legality or illegality of the Abbott-Geneva agreement under the proper antitrust analysis remains to be resolved.

None of Petitioners' attacks on the soundness of the Eleventh Circuit's reasoning has merit. First, Petitioners contend that the payments Abbott made to Geneva under the terms of the agreement are proof positive of the agreement's anticompetitive nature. *Valley Drug* Pet. 25; *Walgreen* Pet. 8-9. As the Eleventh Circuit correctly recognized, however, in the Hatch-Waxman context there is nothing suspect, or even particularly surprising, about the fact that a patent-holder might make payments to a potential infringer as part of a *bona fide* settlement. *Walgreen* Pet. App. 31a-34a. One of the innovations of the Hatch-Waxman amendments was to define the act of filing an ANDA as an act of infringement by the potential generic manufacturer, even before any potentially-infringing sales have been made. Thus, the usual settlement dynamic may be upended in such litigation, "where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a

damages claim to bargain with." *Id.* at 31a. In these circumstances, where parties necessarily are bargaining against a backdrop of imperfect information and the inherent difficulty in predicting the outcome of often-complex patent lawsuits, the patent-holder will often have a legitimate and reasonable incentive to make payments to the alleged infringer as part of a settlement.

Second, Petitioners argue that the fact that Abbott's '207 patent was found invalid many months *after* the agreement was entered into is somehow relevant to the antitrust analysis here. The Court of Appeals properly rejected this contention. The court "[began] with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Id.* at 25a. As the Eleventh Circuit recognized, "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right [of a still-valid patent] through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent." *Id.* at 29a. It was therefore entirely reasonable for Abbott and Geneva to enter into an interim settlement that protected Abbott from substantial lost profits if Geneva launched its product but the patent was subsequently upheld, while at the same time compensating Geneva for its potential loss in profits from delaying its product launch if the patent were subsequently invalidated. The Court of Appeals correctly declined to punish Abbott and Geneva for an interim settlement that allowed the patent challenge to proceed to final judgment and appellate review solely because the legal question underlying the challenge ultimately was resolved in Geneva's favor.

Finally, Petitioners contend that the Eleventh Circuit's analysis fails to take into account an economic theory which Petitioners term "probabilistic patent rights." This theory, which Petitioners did not raise in the District Court or the Court of Appeals, finds no support in antitrust law, which holds that agreements restricting competition in patented goods are not subject to antitrust scrutiny so long as the restraints do not exceed the exclusionary potential of the patents at issue.

According to Petitioners, the supposed vice of the Abbott-Geneva agreement is that it converted what Petitioners characterize as Abbott's "conditional" patent right to exclude infringing competition into an unconditional guarantee of exclusion under the Agreement. But that is simply not true. Under the agreement, Abbott merely converted the right to exclude infringing competition under the '207 patent into a contract right to be free from competition from Geneva's generic product. To the extent that the patent right could be appropriately characterized as "probabilistic," the contract right is equally so.

In April 1998, the '207 patent had never been declared invalid by any court and had the potential to exclude infringing competition until it expired in October 2014. Because the Agreement imposed a far briefer restriction, its restraint fell well within the scope of the '207 patent. A contrary rule would make the settlement of patent litigation virtually impossible where, as here, the patent holder was not amenable to licensing.

* * *

The Eleventh Circuit correctly concluded that under longstanding decisions of this Court, the District Court erred in holding the Abbott-Geneva agreement *per se* illegal without any consideration of Abbott's rights under its Hytrin patents lawfully to exclude unlicensed, infringing competition. Because that decision was correct, review is unwarranted.

CONCLUSION

The petitions for *certiorari* should be denied. If, however, the Court grants review in *Andrx* (No. 03-779), then the Court should grant review in this litigation as well.

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